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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,317	10/15/2003	Susan M. Freier	IBIS0009-101 (ISPH-0794)	8250
34138 7590 07/24/2007 ISIS PHARMACEUTICALS, INC 1896 RUTHERFORD ROAD CARLBAD, CA 92008			EXAMINER VIVLEMORE, TRACY ANN	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 07/24/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/686,317	FREIER ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*; 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) 32-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 and 39-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 14, 2007 has been entered.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 17 is directed to a method of selecting an effective antisense oligonucleotide sequence for inhibition of expression of a preselected target nucleic acid comprising the steps of providing a set of antisense oligonucleotide sequences complementary to a preselected target nucleic acid sequence and selecting a sequence from the set of antisense oligonucleotide

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sequences, wherein the sequence comprises at least one 5'-CCAC-3' motif and does not comprise 5'-GGGG-3' and 5'-GGA-3' sequence motifs. While this claim includes embodiments wherein the selection method is performed in a laboratory setting, this method also includes embodiments wherein the selection steps are made through means of analysis of sequence data by human or computer.

The instant claim is drawn to a process involving the judicial exception of a computational algorithm. A claim drawn to a judicial exception is non-statutory unless the claim includes a practical application of that judicial exception as evidenced by a physical transformation of the claimed invention, or if the claimed invention produces a useful, tangible and concrete final result. In the instant claim, there is no physical transformation by the claimed invention, thus the examiner must determine if the instant claim produces a useful, tangible, and concrete final result.

In determining if the instant claim has a useful, tangible, and concrete final result, the examiner must determine each standard individually. For a claim to be "useful," the claim must produce a final result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete," the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the examiner must reject the claim as non-statutory.

The instant claim does not produce a tangible final result. A tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claim is drawn to a method of selecting effective antisense sequences. However, the last step of the claim merely recites the step of selecting a sequence that does not have particular activity decreasing motifs without indicating a result has necessarily been produced beyond "selecting" a sequence. Thus the instant claims do not require that a result must be produced. Since there is no final result in the claims, the instant claims do not include a tangible final result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or to a user, or by including a physical transformation.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17 and 39-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (US 5,885,970).

The claims are directed to a method of selecting an effective antisense oligonucleotide sequence for inhibition of expression of a preselected target nucleic acid comprising the steps of providing a set of antisense oligonucleotide sequences

complementary to a preselected target nucleic acid sequence and selecting a sequence from the set of antisense oligonucleotide sequences, wherein the sequence comprises at least one 5'-CCAC-3' motif and does not comprise 5'-GGGG-3' and 5'-GGA-3' sequence motifs. In specific embodiments the sequences are synthesized as test oligonucleotides that may be chimeric or comprise 2'-substitutions and are tested *in vitro* for their ability to modulate a target nucleic acid.

Bennett et al. disclose antisense oligonucleotides targeted to human protein kinase C, several of which have 5'-CCAC-3' motifs and no 5'-GGGG-3' or 5'-GGA-3' motifs (see, for example, SEQ ID NOs: 1, 34, 57, 67, 79 and 81). At columns 7-8 Bennett et al. disclose that the oligonucleotides may contain 2'-substitutions or be synthesized as chimeras. In the working examples Bennett et al. disclose the synthesis and *in vitro* testing of these sequences for their ability to inhibit human protein kinase C and are considered to have selected sequences with the CCAC motif and lacking the GGGG and GGA motifs.

Thus, Bennett et al. disclose all limitations of and anticipate claims 17 and 39-42.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

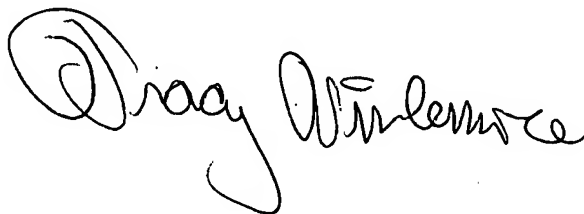
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
July 19, 2007

A handwritten signature in black ink, reading "Tracy Vivlemore", written in a cursive style.